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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,560	12/28/2000	Jaan Noolandi	XER 2 0399	6443
7590	04/05/2004		EXAMINER	
Albert P. Sharpe, III, Esq. Fay, Sharpe, Fagan, Minnich & McKee, LLP 1100 Superior Avenue, 7th Floor Cleveland, OH 44114-2518			SIEW, JEFFREY	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 04/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/750,560	NOOLANDI ET AL.
	<b>Examiner</b> Jeffrey Siew	<b>Art Unit</b> 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 16 December 2003.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-5,7-11 and 13,15-29 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 7,13 and 15-26 is/are allowed.  
 6) Claim(s) 1-5,8-11 and 27-29 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 06 August 2002 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date, _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Nasu et al (US5,246,866 September 21, 1993).

Nasu et al teach a DNA sequencing apparatus in which fluorescently labeled fragments are subject to electrophoresis and illuminated and exposed to detection to create an image corresponding to gel (see whole doc. esp. abstract). They teach the apparatus (see Figure 7) with an electrophoresis unit 73 (separation apparatus) with an upper electrode 74a and lower electrode 74b, which applies an electric field to separate fragments and optical sensor 78 (detector) and optical source 71 (illumination means). The apparatus contains a gel which is a polymer solution. The apparatus is attached to processing unit which can create image corresponding to gel (see Figure 5-7). The light receiving elements are arranged perpendicular to the direction of electrophoresis (see col 4 line 5). The image represents the same type of the gel (see col. 4 lines 31-37 & figure 2). The detector scans the full width of the array of samples in gel (see figure 7). Detection occurs over several time periods (see col. 7 line 59).

The response filed 12/16/03 has been fully considered and deemed not persuasive. The response have amended claim 1 & 9 to state that the “full width array scanner of scanning entire width of separation apparatus simultaneously”. The response refers to the specification page 9 line 27 to provide support for the amendment. However, the specification refers to scanning in a direction parallel to the length of the capillary tubes. The term “width” instead may still refer to the direction that is perpendicular to the direction of sample along the capillary tubes. Nasu apparatus does teach a full width array scanner that scan the entire width of the apparatus (see figure 1 item 21). The 102 rejection and the 103 rejection based on Nasu are maintained.

2. Claims 1-3,8,9, 11,27,28 & 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Mackay (US4,874,492 oct. 17, 1989).

Mackay et al teach a method of imaging bands of DNA using a charge couple device. They separate bands using electrophoresis apparatus and use light sensitive CCDs to create a electronic representation of two dimensional full image (see whole doc. esp. col. 2 lines 46-64).

The response argues that Mackay do not teach full width array scanner that scans the entire width of the apparatus simultaneously. Mackay et al do teach such a limitation in that the CCD device scans the whole length of the gel (see figure 1). The response next argues that CCd is different from the scanner as discussed in the specification on page 13 lines 16-17). While the claims are read in light of the specification, limitations in the specification are not read into the claims. The broad reading of the claims may be reasonably interpreted to encompass the Mackay reference. The rejection is maintained.

Mackay et al would also read on new claims 27 & 28. While it was noted in the previous office action that the basis of allowability of claim 20 was the limitation “laser is attached to the rear of the detector”. New claims 27 & 28 do not recite such a limitation. The claims recite illumination source attached to means for detecting” which is a much broader limitation. Mackay et al teach the UV source that is indirectly attached to the detector through a computer that controls both detector and light source (see col.6 line 48-55).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 & 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al (US5,274,240 Dec, 28, 1993) in view of Birnbaum et al (US5,627,643 May 6, 1997).

Mathies et al teach the capillary gel electrophoresis for DNA sequencing (see whole document & col. 6 line 6 & col. 6 line 61).

Mathies et al do not full scan imaging.

Birnbaum et al teach a capillary electrophoresis apparatus to separate fluorescence (see whole doc. esp abstract). They teach an electrophoretic separation using an electric field (separation device) (see col. 1 line 26). They teach thin capillaries (see col. 1 line 29). In Figure 1 they teach a laser which irradiates samples along the capillary (see col. 2 line 20). They teach a CCD detector for generating an electronic image of the appearance of the capillary (see col. 2 lines 24-26 & figure 1). The detection is along the direction of migration (col. 3 line 32). They detect over various time intervals (see col. 2 line 22).

One of ordinary skill in the art would have been motivated to apply Birnbaum et al's detection device to in order to provide real time detection of the various labels simultaneously. Birnbaum state that the whole capillary may be examined momentarily allowing for simultaneous detection which provides a quicker evaluation (see col. 1 lines 40-65). It would have been prima facie obvious to apply Birnbaum et al's device to detect in capillary electrophoretic device in order to detect simultaneously and in real time the separation of DNA fragments.

The response states that the 103 rejections based on the combination Mathies and Birnbaum et al should not be maintained because neither reference teaches scanning the entire width of the separation apparatus simultaneously. Birnbaum do teach scanner that scans the entire distance in the direction of the samples in the capillary tube. Moreover, it would have been prima facie to combine the Mathies teaching of separation of DNA samples in Birnbaum's scanner. The rejection is maintained.

4. Claims 5 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nasu et al (US5,246,866 September 21, 1993) in view of Frnakel et al

Nasu et al teach a DNA sequencing apparatus in which fluorescently labeled fragments are subject to electrophoresis and illuminated and exposed to detection to create an image corresponding to gel (see whole doc. esp. abstract). They teach the apparatus (see Figure 7) with an electrophoresis unit 73 (separation apparatus) with an upper electrode 74a and lower electrode 74b, which applies an electric field to separate fragments and optical sensor 78 (detector) and optical source 71 (illumination means) (see col.. The apparatus contains a gel which is a polymer solution. The apparatus is attached to processing unit which can create image corresponding to gel(see Figure 5-7). The light receiving elements are arranged perpendicular to the direction of electrophoresis (see col 4 line 5). The image represents the same type of the gel (see col. 4 lines 31-37 & figure 2). The detector scans the full width of the array of samples in gel (see figure 7). Detection occurs over several time periods(see col. 7 line 59).

Nasu et al do not teach lithographically etched channels.

Frankel et al teach lithographically etched channels in glass substrates(see col. 3 line 63-65).

One of ordinary skill in the art would have been motivated to apply Frankel et al's lithographically etched channels in glass substrates to Nasu et al's device in order to perform rapid and plurality separations. Frankel et al teach that channels provide for increased number of separations. It would have been prima facie obvious to apply Frankel's etched channels to Nasu

et al's device in order to increase the number of samples that would be assayed during a single run.

### **THE FOLLOWING IS A NEW GROUND OF REJECTION**

#### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5,8, 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The term "width" in claim 1 & 9 renders claims 1-5,8, 9-11 indefinite. It is unclear as to what direction the term would refer to e.g. perpendicular or parallel to the direction of the samples.

### **SUMMARY**

6. Claims 7,13,15,16-19 and 20-26 are allowable. There is no prior art that teach or suggest the claimed method or device with amorphous silicon 2 dimensional image sensor array . There

is no prior art that teach or suggest the claimed device where the laser is attached to the rear of the detector.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew who can be reached at 571-272-0787. The e-mail address is [Jeffrey.Siew@uspto.gov](mailto:Jeffrey.Siew@uspto.gov). However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach

the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (571)272-0534.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center FAX is (703)-872-9306.

  
**JEFFREY SIEW**  
**PRIMARY EXAMINER**

March 24, 2004